

Bottlenecks in the establishment of Biotech-based Companies

MCTIP - Dirección Nacional de Relaciones Internacionales

Presidencia de la Nación

Buenos Aires, 5-7 October 2011

AKIRA HOMMA

Chairman Policy & Strategy
Council

Public Production of Vaccines at

Bio-Manguinhos/Fiocruz

07 October, 2011



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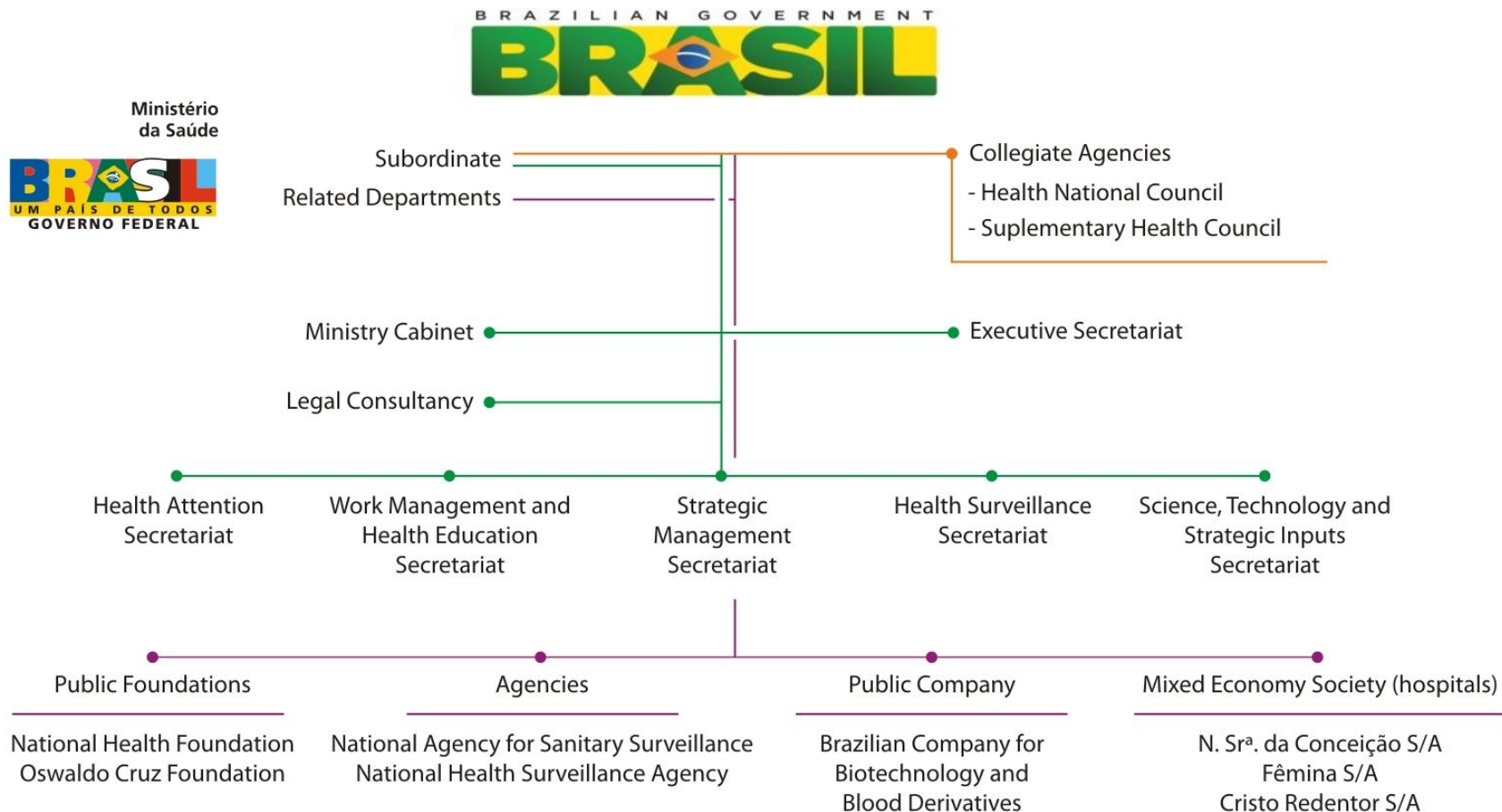


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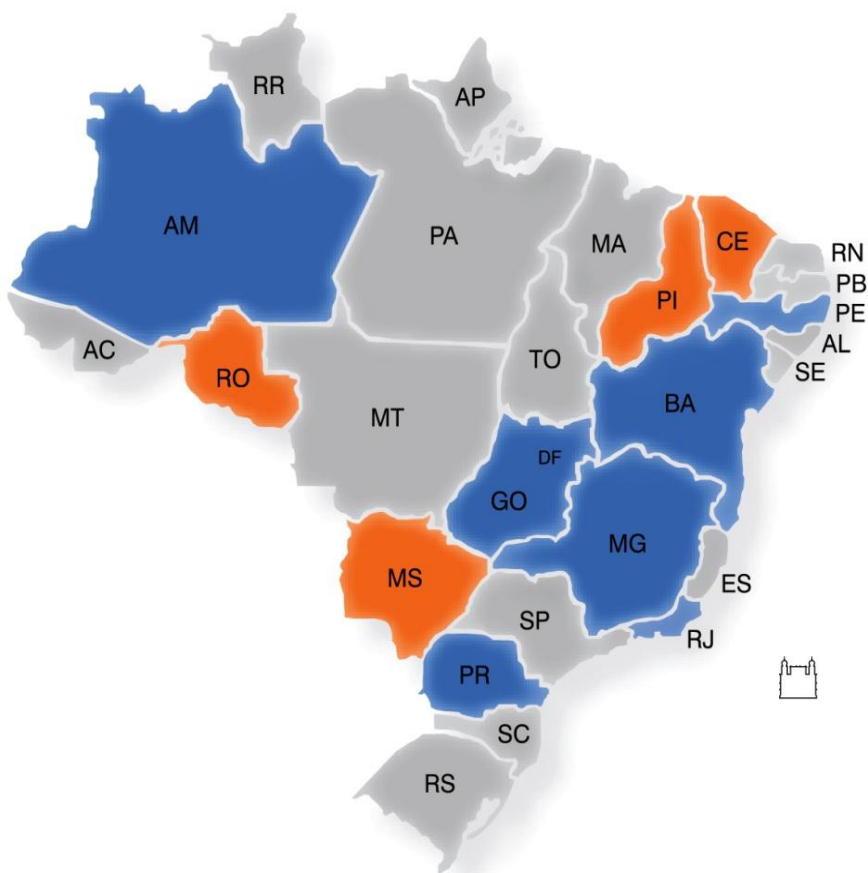


Ministry of Health Organizational Chart



Source: MoH site

Geographic Distribution



■ Fiocruz's units
■ New units

- Presidency/Central Administration
- 14 Technical-Scientific Units

Tech Devel & Production: Bio-Manguinhos and Farmanguinhos

Biomedical Research: IOC(RJ), ICC(PR), CPqAM(PE), CPqGM(BA), CPqL&MD(AM), CPqRR(MG)

Clinical Research: IFF(RJ) & IEC(RJ)

Post-graduation and technical schools: ENSP(RJ) & EPJV(RJ)

Documentation, information and historical units: COC(RJ), CICT(RJ)

- 1 Support unit: CECAL(lab Animals Breed)(RJ)
- 1 Specialized service: INCQS(RJ)
- 4 Administration units and 1 office in Brasilia

Total: 20 units and 4 new Technical Scientific Units: CE, MS, PI, RO.

Geographic Distribution



- In 2008 opened an Office in Mozambique, Africa, for training courses in masters, doctoral and post graduation.
- Support the implementation of the pharmaceutical plant that will produce the retroviruses drugs.

Figures



Fiocruz

- About 11.800 employees
- 1.065 PhD, 1.047 Masters and 1.366 post graduated
- 2.900.000 m² built area (headquarters RJ)



Bio-Manguinhos

- About 1.300 employees
- 46 PhD, 136 Masters and 223 post-graduated
- 193.000 m² built area

Our Mission and Vision



MISSION

Contribute to the improvement of Brazilian public health standards through innovation, technological development and production of immunobiologicals and service provision to attend the country's health needs.

VISION

To become the technological base of the Brazilian Republic for the biopharmaceutical sector, and to lead the supply of goods and services of epidemiological, biomedical and sanitary interest.



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Timeline

Bio-Manguinhos is created to organize to develop and produce vaccines and to supply to the National Immunization Program

1976

1978

Start production of kits for lab diagnostics needed to MoH

1986

IFI HIV-1 diagnostic kits for the National Program on STD/Aids

2001

WHO pre-qualification of the YFV 5/50 doses

2002

First exports to UN agencies

2006

supply of biopharmaceutical drugs for MoH

2007

WHO pre-qualification of the YFV 10 doses

2008

WHO pre-qualification of Polysaccharide Men AC

2011

Beginning of NAT HIV/HCV services to MoH



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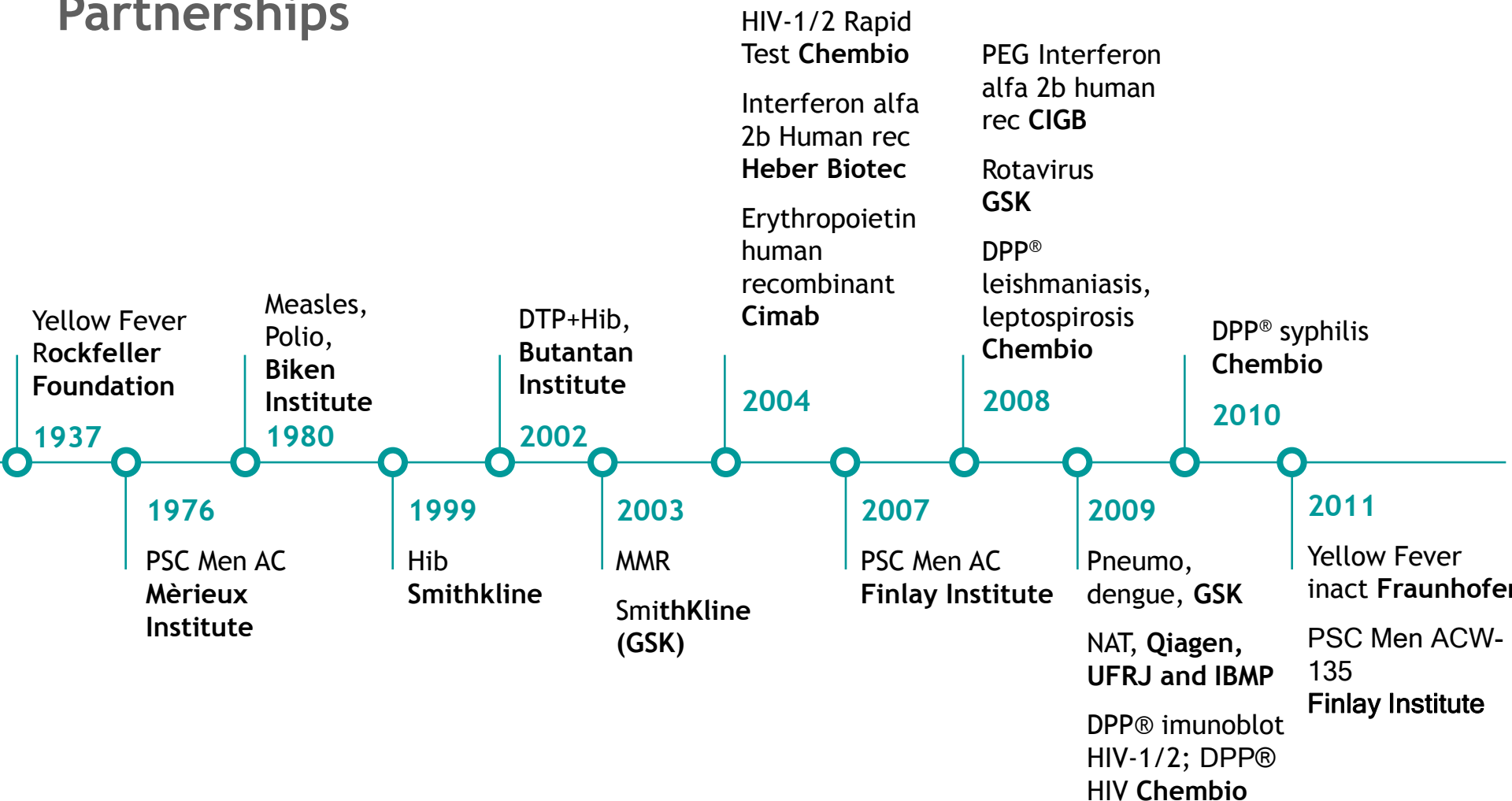


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Technology Transfer & Partnerships



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MoH Demand - 2011 BM 8 Vaccines - (doses)



- Yellow Fever: 32.358.440
- Measles, Mumps and Rubella: 27.000.000
- Oral Polio: 20.000.000
- DTP*+Hib: 14.000.000
- 10-valent Pneumococcal**:
13.000.000
- Rotavirus**:
4.000.000
- Polysaccharide Men AC: 80.000
- Hib: 70.000

> 56% MoH demand

Total: 110.508.440

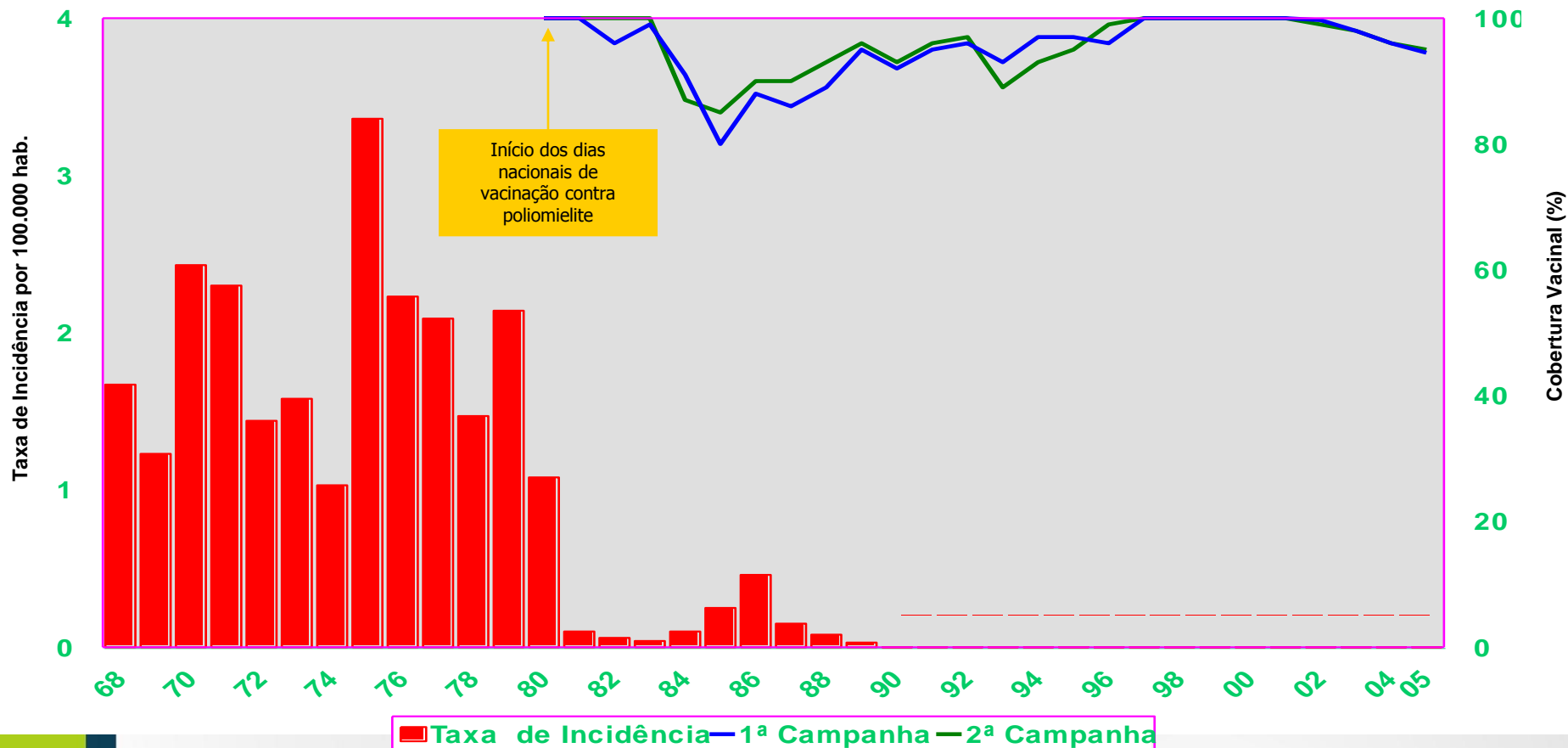


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Programa Nacional de Imunizações

Incidência de poliomielite e cobertura vacinal com a VOP*, em campanhas nacionais de vacinação, Brasil, de 1968 a 2005

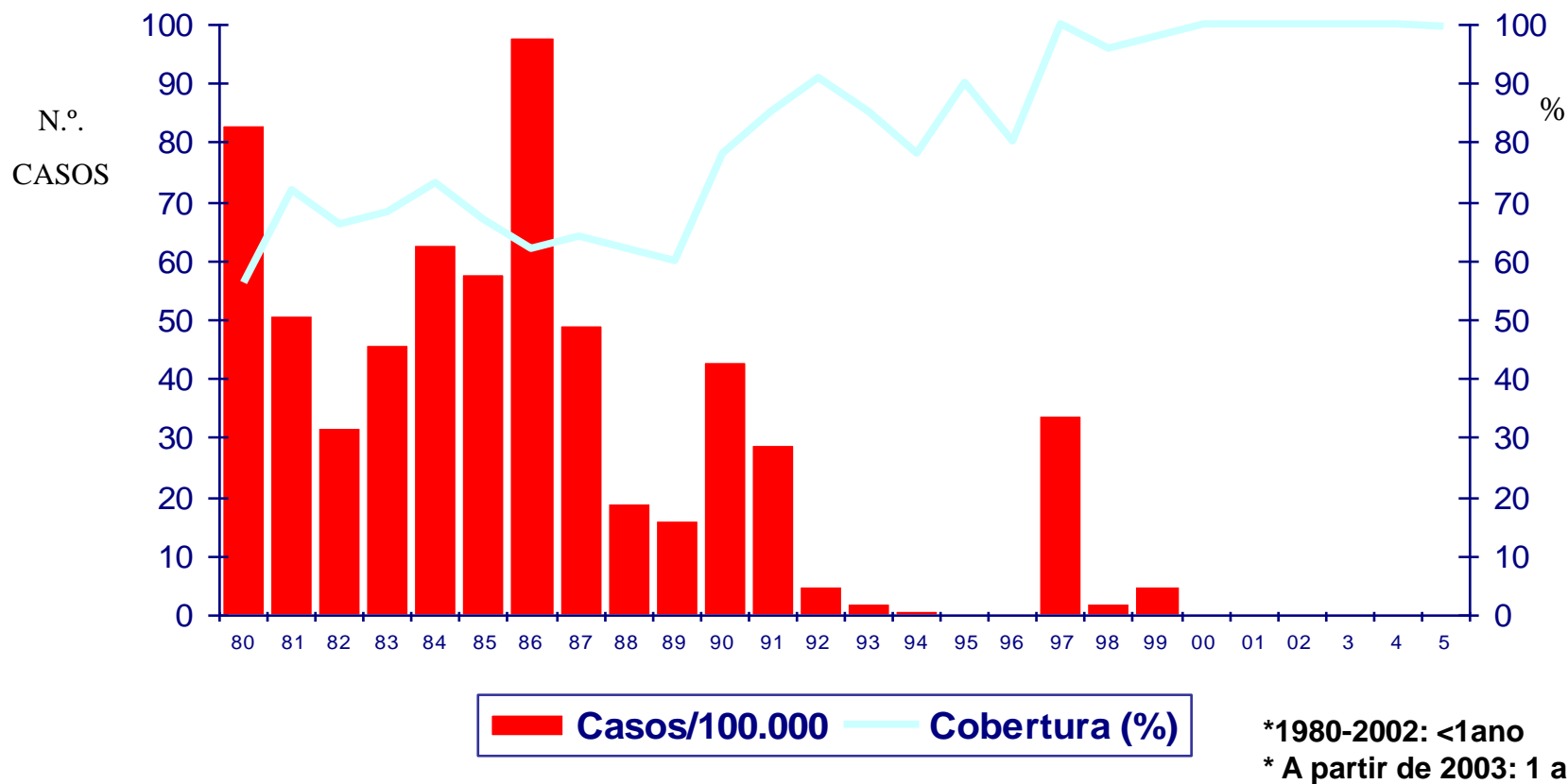


* VOP: Vacina oral contra poliomielite.

Fonte: Ministério da Saúde SI-PNI.

Programa Nacional de Imunizações

Incidência de Sarampo e Cobertura Vacinal, Brasil, 1980 a 2005



Contribution to international public health

Vaccines: Yellow Fever and Polysaccharide Men AC / 2002 - 2011



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MoH Demand/2011 -15 Kits Lab Diagnostics (in tests)



- Chagas Disease: 153.936
- Human Leptospirosis: 38.400
- Canine Leishmaniasis: 3.032.960
- DPP® Leishmaniasis: 1.000.000
- Schistosomiasis: 1.260.000
- IFA HIV 1: 50.000
- DPP® imunoblot HIV: 150.000
- DPP® HIV 1/2: 1.000.000
- DPP® syphilis: 800.000

Total: 6.887.516



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MoH Demand - 2011

2 Biopharmaceuticals (in vials)



Interferon alpha 2b human recombinant

- 3 MUI: 102.136
- 5 MUI: 33.881
- 10 MUI: 5.016

Erythropoietin human recombinant

- 4.000 UI: 9.655.795
- 2.000 UI: 1.080.740

Total: 10.877.568



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Technological Development - 2011

	Preclinical Development	Clinical Development			TT	F4	Total
		F1	F2	F3/ME			
Bacterial vaccines	4	-	2	-	1	-	7
Viral vaccines	8	-	-	3	2	1	14
IVD Reagents	3	1	-	-	2	1	6
Biopharmaceuticals	2	-	-	2	3	-	8
Total	17	8			8	2	35



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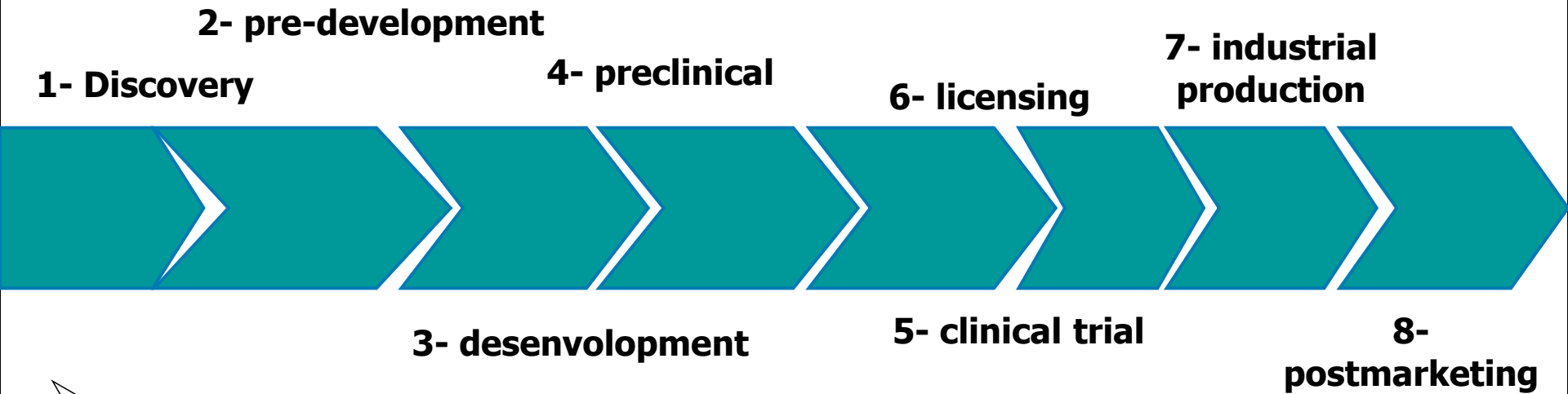
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■ Steps of vaccine innovation - 10-20 years



- **Tecnology prospection**
- **Intelectual property, patents**
- **Projetos pluri-anuais;**
- **Management – go-no-go**

The Integrated Center for Prototypes, Biopharmaceuticals and Kits for Laboratory Diagnostic - CIPBR



Prototype Plant (virus and bacteria)

- 1st pilot plant in Brazil - Good Laboratory Practices (GLP), Good Manufacturing Practices (GMP) and Biosafety to establish scale-up production parameters for experimental and clinical trials batches

- Fiocruz Service Projects and other public & private institutions

Funding: BNDES, MoH, Bio-Manguinhos

- Biopharmaceutical Plant

- 1st plant for the production of Active Pharmaceutical Ingredients for biopharmaceuticals in Brazil

Funding: MoH

- Kits for Laboratory DiagnosticL

- The largest production plant of Reagents for Diagnosis in Brazil

- Expansion of the supply and quality of Reagents for Diagnosis provided to the Ministry of Health programs, essential to the country's epidemiological surveillance

Funding: MoH, BNDES, Bio-Manguinhos



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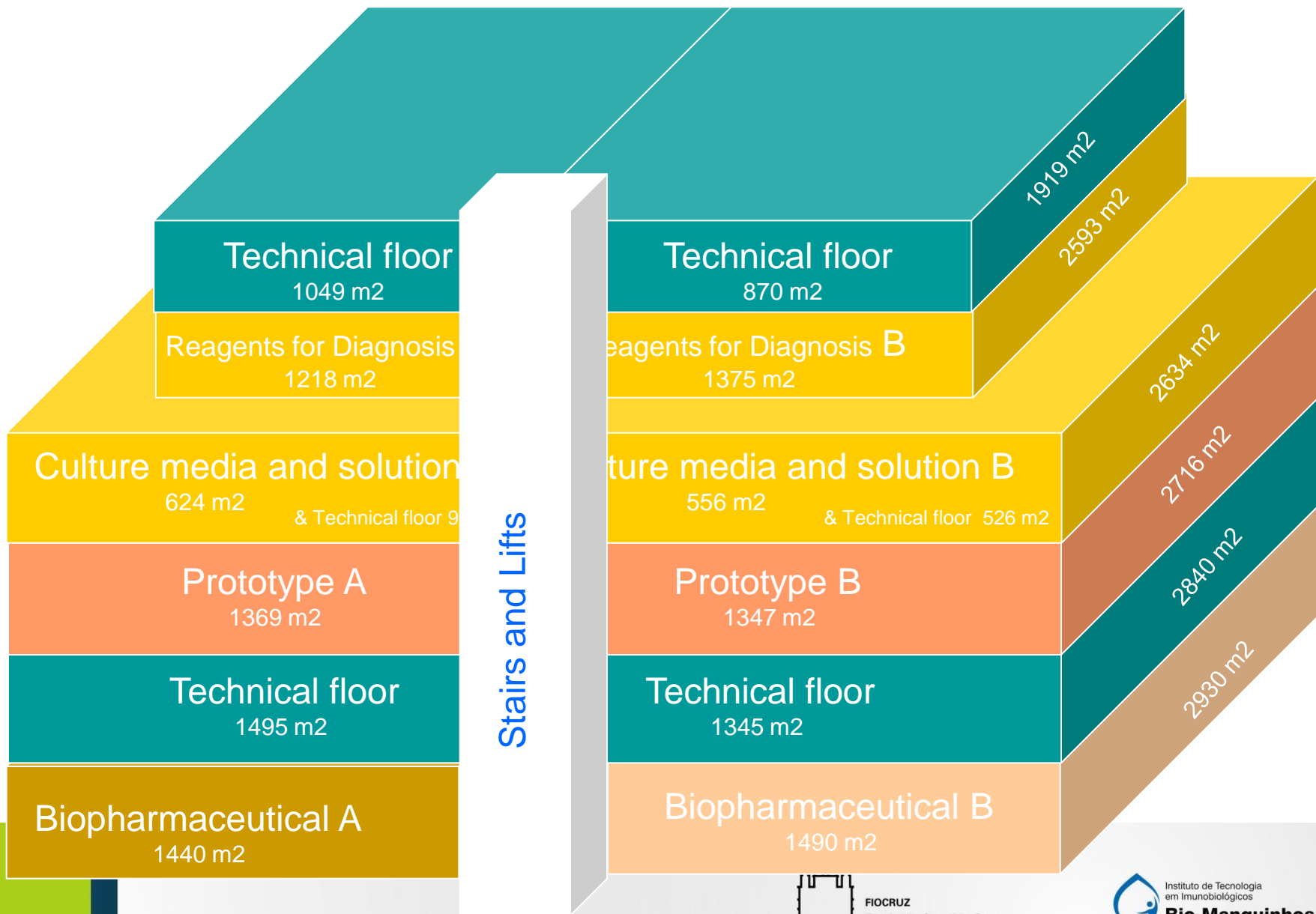
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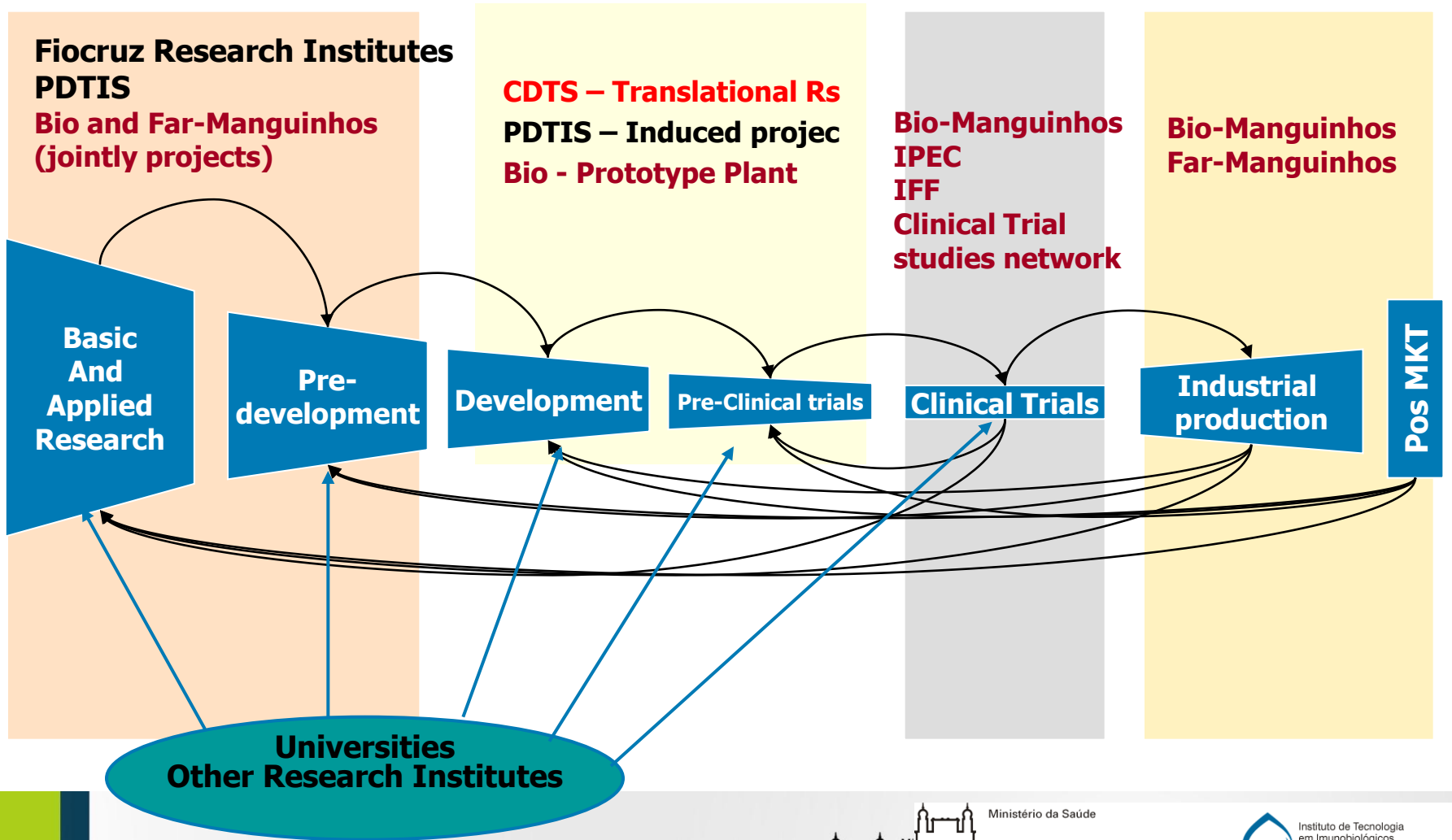


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Fiocruz Innovation System



CDTS - Center for Technological Development in Health - Translational Research



New Facility - Final Processing Center

- modern and up-to-date facility - compliance with the new GMP requirements
- expansion of production capacity (NIP and exports)
- increase production efficiency



Built area: 90.000 m²

Required investment: R\$ 800 million



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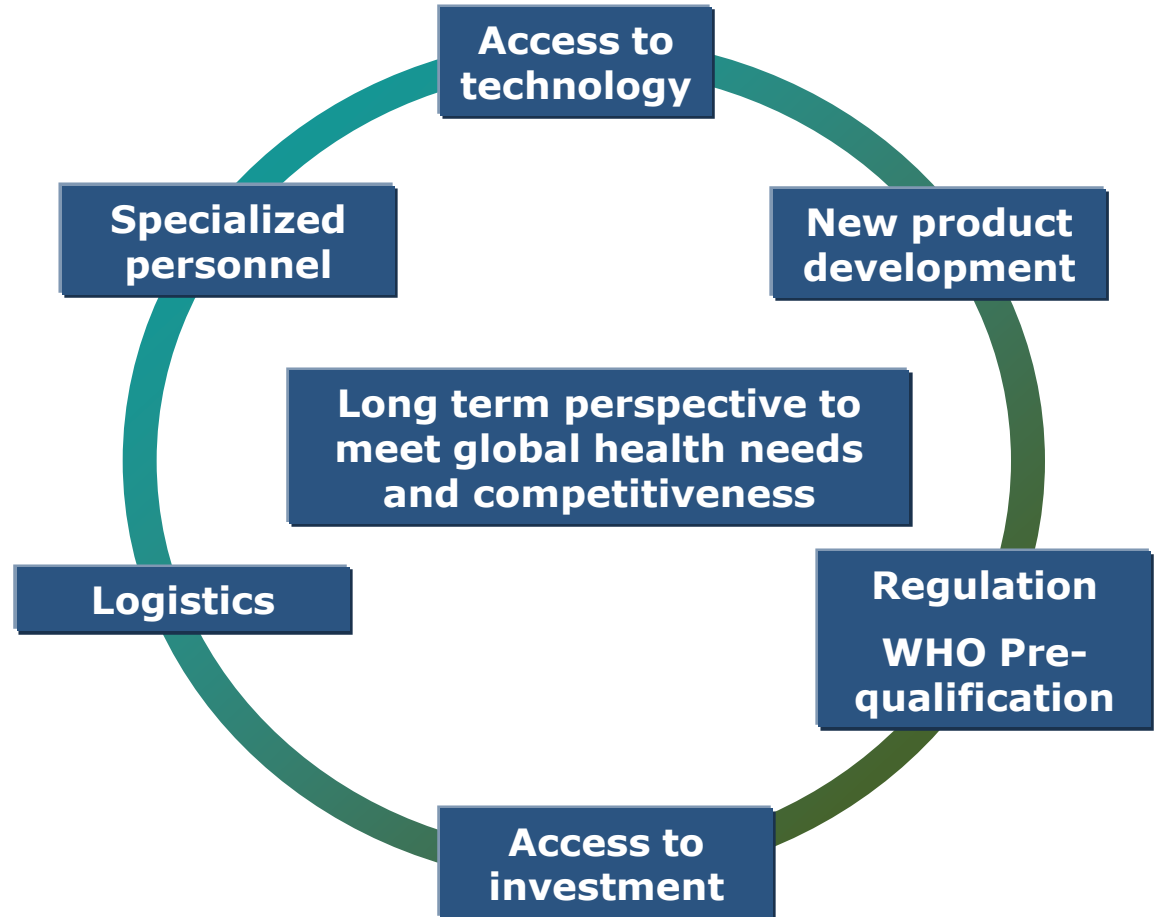


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Challenges for the Developing World Vaccine Manufacturers

- Must meet the national demand of classical vaccines and incorporate technologies of production of new vaccines –



Regulatory issues

- **Increasing stringent regulatory requirements** → require high investment
 - Facility and area classification
 - Validation of equipment and facility
 - Validation of production process, QC, QA
 - Qualified personnel
 - Suppliers
- **WHO Pre-qualification**
 - Functioning Local Regulatory Authority
 - Enforces the same stringent requirements established by international regulators

Access to technology, new product development

❑ Vaccine innovation

- ❑ high investment is a must, long period of maturation, specialized personnel and facilities, GLP, GMP, GCP compliance and bear uncertainty of results and return

■ Vaccine manufacturing is a high fixed cost entrepreneurship

- Industrial production scale - reducing cost of production
- Increasing demand does not necessarily imply the need of greater number of manufacturers
 - Market size is same

❑ New technologies of production - monopoly, oligopoly of big pharma

❑ Increased interest of bigpharma in the emerging markets

- - *Partnership - tech transfer - is essential to incorporate rapidly new technology of production*
- - Use of Buyer Power to obtain technology

Financing new facilities

- New production facility requires huge investment
- Limited access to funds for investments --- high cost of financial resources
- Need fiscal incentive to build new enterprises
- Need sustainable and long term of assured demand so that new production capacity is not an uncertain investment
- The constraints of the Government budget turns national vaccine procurement unstable
- The public manufacturers must obtain a more flexible administrative and managerial tools



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Long term perspective

- Policy makers and industry must have a long term perspective - sustainable policy
- Vaccine manufacturing is not a commodity industry
 - Industry must avoid shortages and be socially committed
 - Shortages has long term consequences
 - Strengthening the local Research and Technological capabilities is crucial
 - To create new structuring projects
 - To develop new technologies
 - To bring new vaccines at affordable prices
- Must increase South-South partnership



Summing up

- Creating industrial capabilities is not an easy task. It depends on a very complex and delicate balance

Production and Supply side

- Access to modern technology
- Access to investment
- Specialized personnel
- Logistics
- Regulation and pre-qualification

Demand side/NIP

- Private and/or public sustainable demand
- Awareness
- Social welfare network
- Capability to introduce underused and new vaccines

Policy side

- Commitment to public health
- Strategies to overcome technological dependency
- Long term perspective
- Guarantee of market in a long perspective



Thank you!

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